Analysis of Long-Term Efficacy of Nipocalimab in Myasthenia Gravis: Open-Label Extension of the Vivacity-MG3 Trial

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Key Takeaways

- **Patients** who **continued nipocalimab+SOC** in OLE phase showed **sustained improvements in MG-ADL and QMG scores** up to Week 48 (i.e., OLE Week 24) of Vivacity-MG3 study

Introduction

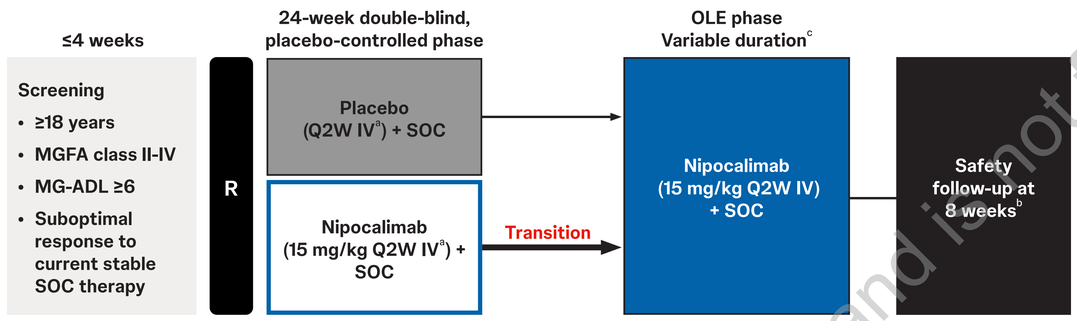
- Generalised myasthenia gravis (gMG) is a chronic autoimmune disease caused by autoantibodies targeting the neuromuscular junction
  - It is characterized by generalized weakness in ocular and skeletal muscles affecting the daily functioning and Quality of Life[1,2]
- **Vivacity-MG3 study:** A double-blind (DB), 24-week, phase 3 study demonstrated statistically significant and clinically meaningful improvements in Myasthenia Gravis-Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) scores with nipocalimab+standard-of-care (SOC) treatment versus placebo+SOC[3]
  - The findings from this study supported the recent United States Food and Drug Administration approval of nipocalimab.[4] The European Medicines Agency Committee for Medicinal Products for Human Use recently (September 2025) recommended authorizing the marketing of nipocalimab added to standard-care therapy for treatment of gMG in adults and adolescents (aged ≥12 years of age) who are anti-AChR or anti-MuSK antibody positive.[5]
- Patients on nipocalimab+SOC in the DB phase of Vivacity-MG3, could continue to receive active drug in ongoing open-label extension (OLE) allowing the assessment of long-term efficacy of nipocalimab+SOC

Objective

- **To assess the long-term efficacy of nipocalimab+SOC in OLE phase in patients transitioned from nipocalimab+SOC arm of DB phase of the Vivacity-MG3 study**

Methods

Study Design



[a]All patients received the loading dose of placebo or nipocalimab 30 mg/kg at week 0 and then started placebo or nipocalimab 15 mg/kg Q2W IV from Week 2 to Week 24; [b]Patients who withdraw or discontinue after receiving any amount of study intervention are required to complete a safety follow-up visit 8 weeks after their last dose; [c]In the EU, the OLE phase will be up to 240 weeks. **DB**=Double-blind; **IV**=Intravenous; **MG-ADL**=Myasthenia Gravis-Activities of Daily Living; **MGFA**=Myasthenia Gravis Foundation of America; **OLE**=Open-label extension; **Q2W**=Every 2 weeks; **R**=Randomized 1:1; **SOC**=Standard-of-care.

Assessments based on MG-ADL and QMG

Improvement in MG-ADL and QMG total scores from DB baseline

- Mean changes in MG-ADL and QMG scores at DB Week 24 through Week 48 in OLE
  - Within-group mean changes were examined using paired t-test
- Proportion of patients achieving Meaningful clinical improvements (MCI; ≥2-point improvement[6,7] from DB baseline in MG-ADL total score [MG-ADL-2])
- Proportion of patients achieving Minimal symptom expression (MSE; MG-ADL score of 0 or 1)
- Proportion of patients with sustained MCI and MSE for ≥8 weeks
- Percentage of time spent in MCI and MSE

Results

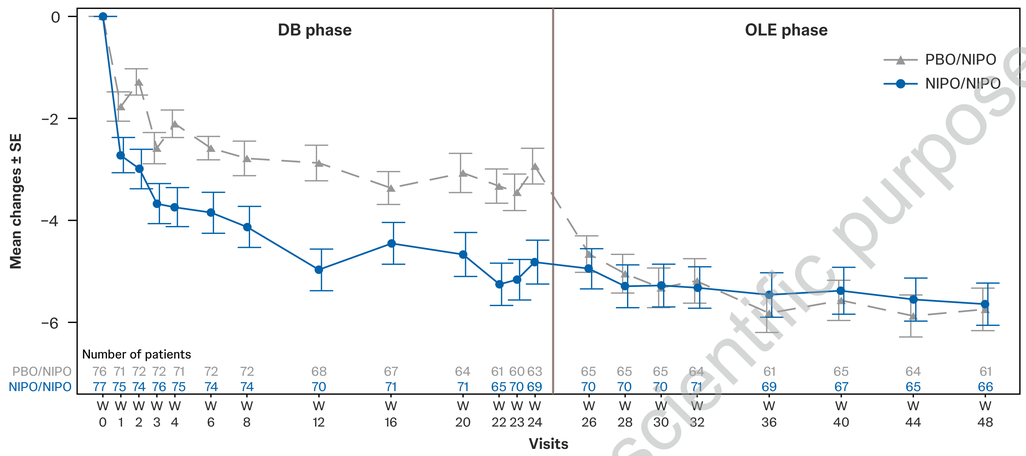
Analysis population and exposure

- Overall, 77 patients from nipocalimab+SOC arm completed DB phase and 71 of them continued on nipocalimab+SOC in OLE phase
- Data were collected up to Week 48 (DB 24 weeks + OLE 24 weeks), (cutoff: 23-August-2024)
- The mean (standard deviation [SD]) duration of nipocalimab exposure was: 90.3 (27.27) weeks, n=71
  - 71 (100.0%) patients had nipocalimab exposure for ≥6 months
  - 67 (94.4%) patients had nipocalimab exposure for ≥12 months

Improvements in MG-ADL total score

- Mean (SD) MG-ADL score at DB baseline (Week 0): 9.40 (2.78)
- Improvements in **MG-ADL score at Week 24** were **maintained through Week 48 (Figure 1)**
- Mean (SD) change from baseline (CFB) in MG-ADL score:
  - **At Week 24:** −4.82 (3.57), p<0.001
  - **At Week 48:** −5.64 (3.36), p<0.001

Figure 1: Mean improvements in MG-ADL score

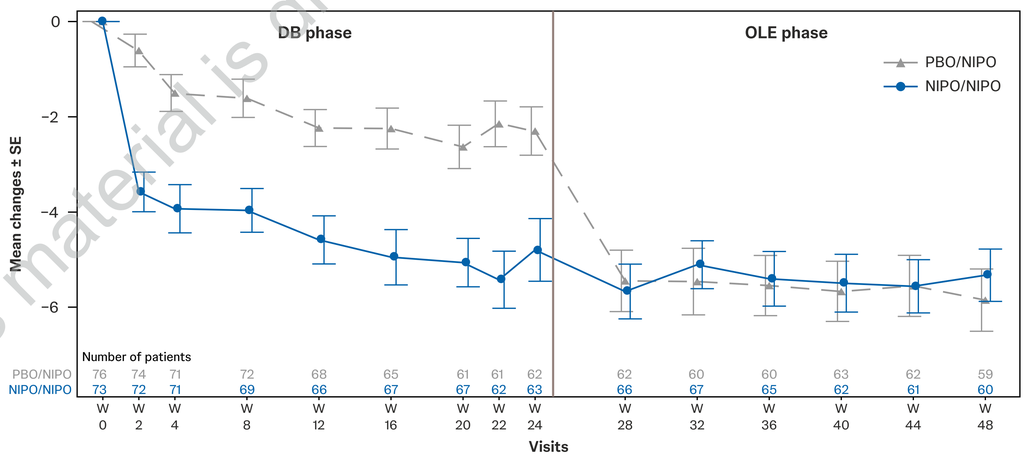


Note: Negative change in score indicates improvement. PBO/NIPO: patients from PBO+SOC arm of DB phase received NIPO+SOC in OLE phase. NIPO/NIPO: Patients in NIPO+SOC arm in DB phase continued to receive NIPO+SOC in OLE phase. P-value for comparison of MG-ADL total score change from baseline significantly different from zero using a one-sample t-test. **DB**=Double-blind; **MG-ADL**=Myasthenia Gravis-Activities of Daily Living; **NIPO**=Nipocalimab; **OLE**=Open-label extension; **PBO**=Placebo; **SE**=Standard error; **SOC**=Standard-of-care; **W**=Week.

Improvements in QMG total score

- Mean (SD) QMG score at DB baseline (Week 0): 15.10 (4.78)
- Improvements in **QMG score at Week 24** were **maintained through Week 48 (Figure 2)**
- Mean (SD) CFB in QMG score:
  - **At Week 24:** −4.79 (5.22), p<0.001
  - **At Week 48:** −5.33 (4.25), p<0.001

Figure 2: Mean improvements in QMG score

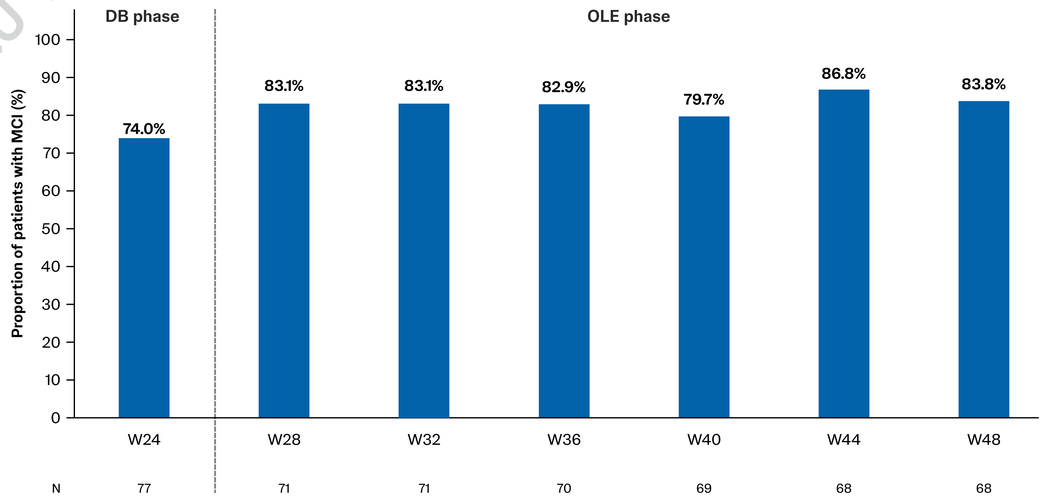


Note: Negative change in score indicates improvement. PBO/NIPO: patients from PBO+SOC arm of DB phase received NIPO+SOC in OLE phase. NIPO/NIPO: Patients in NIPO+SOC arm in DB phase continued to receive NIPO+SOC in OLE phase. P-value for comparison of QMG total score change from baseline significantly different from zero using a one-sample t-test. **DB**=Double-blind; **NIPO**=Nipocalimab; **OLE**=Open-label extension; **PBO**=Placebo; **QMG**=Quantitative myasthenia gravis; **SE**=Standard error; **SOC**=Standard-of-care; **W**=Week.

Proportion of patients achieving and sustaining MCI

- At Week 48, **57 (83.8%) of patients achieved MCI** in MG-ADL (MG-ADL-2) **(Figure 3)**
  - **Mean (SD) time to earliest MCI** was **4.6** (7.87) **weeks**
  - **Sustained MCI for ≥8 weeks** was observed in **66** (85.7%) patients
- **Percentage of time with MCI**
  - **Mean (SD)** percentage of time[b] with MCI up to Week 48: **74.0** (33.33)%
  - **≥50% study time** with MCI, n (%): 55 **(77.5%)** patients
  - **≥75% study time** with MCI, n (%): 49 **(69.0%)** patients

Figure 3: Proportion of patients achieving MCI[a] in MG-ADL score through Week 48

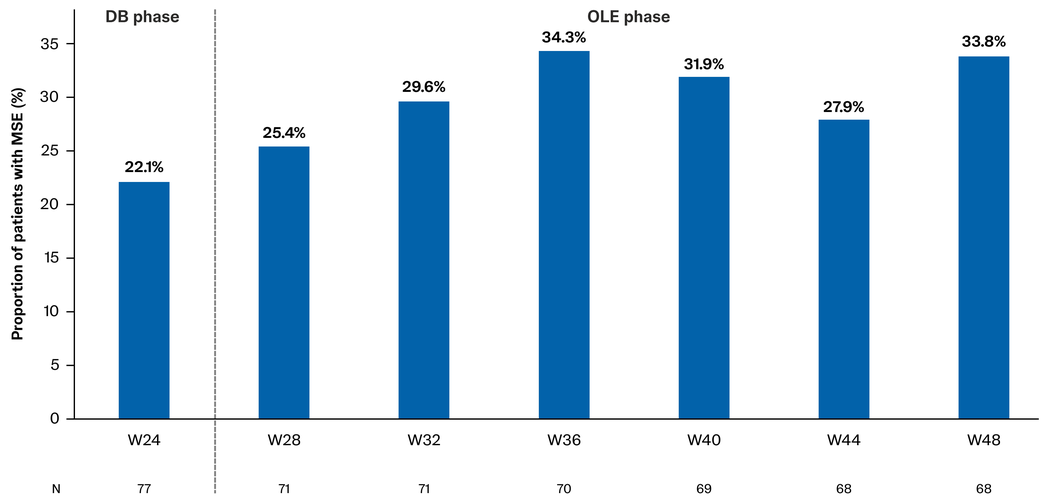


Note: Any patient without a score at a given week were considered as not meeting the MCI conditions. [a]MCI is defined as MG-ADL total score improvement of at least 2 points from OLE baseline. [b]Percentage of time with improvement calculated as cumulative days of improvement divided by number of days in study up to OLE Week 24. The number of days in study up to OLE Week 24 is calculated as OLE Week 24 date (or early termination date if earlier) minus DB baseline date. **DB**=Double-blind; **MCI**=Meaningful clinical improvement; **MG-ADL**=Myasthenia Gravis-Activities of Daily Living; **OLE**=Open-label extension; **W**=Week.

Proportion of patients achieving and sustaining MSE

- 31.2% of patients achieved MSE at anytime during the DB phase and 22.1% achieved MSE at Week 24
- At Week 48, **23 (33.8%) of patients achieved MSE** in MG-ADL (MG-ADL-2) **(Figure 4)**
  - **Mean (SD) time to earliest MSE** was **17.5** (18.70) **weeks**
  - **Sustained MSE for ≥8 weeks** was observed in **24** (31.2%) of patients
- **Percentage of time with MSE**
  - **Mean (SD)** percentage of time[b] with MSE up to Week 48: **20.2** (33.39)%
  - **≥50% study time** with MSE, n (%): 15 **(21.1%)** patients
  - **≥75% study time** with MSE, n (%): 11 **(15.5%)** patients

Figure 4: Proportion of patients achieving MSE[a] in MG-ADL score through Week 48



Note: Any patient without a score at a given week were considered as not meeting the MSE conditions. [a]MSE is defined as MG-ADL total score of 0 or 1. [b]Percentage of time with MSE calculated as cumulative days of MSE divided by number of days in study up to OLE Week 24 (i.e., Week 48). The number of days in study up to OLE Week 24 is calculated as OLE Week 24 date (or early termination date if earlier) minus DB baseline date. **DB**=Double-blind; **MG-ADL**=Myasthenia Gravis-Activities of Daily Living; **MSE**=Minimal symptom expression; **OLE**=Open-label extension; **W**=Week.

PRESENTED AT: American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting; San Francisco, CA, USA; October 29–November 1, 2025. **REFERENCES: 1.** Gilhus NE, et al. Myasthenia gravis. *Nat Rev Dis Primers.* 2019;5:30. **2.** Dresser L, et al. *J Clin Med.* 2021;10:2235. **3.** Antozzi C, et al. *Lancet Neurol.* 2025;24(2):105–116. **4.** IMAAVY™ (nipocalimab-aahu) injection for intravenous use [Package Insert] Horsham, PA; Janssen Pharmaceutical Companies, 2025. **5.** European Medicines Agency. Imaavy™. European Medicines Agency; 2025 Sep 22. https://www.ema.europa.eu/en/medicines/human/ EPAR/imaavy **6.** Muppidi S, et al. *Muscle Nerve.* 2011;44(5):727–731. **7.** Muppidi S, et al. *Ann N Y Acad Sci* 2012;1274:114–119. **ACKNOWLEDGMENTS:** Kalpana Tilekar, PhD (SIRO Medical Writing Pvt. Ltd., India.) and Doyel Mitra, PhD (Johnson & Johnson) provided editorial assistance. Layout design and reformatting for this encore presentation were provided by Mugdha Rokade (SIRO Medical Writing Pvt. Ltd., India), with funding from Johnson & Johnson. **DISCLOSURES: Nicholas J. Silvestri:** Consultant/advisor for Alexion, Amgen, Annexon, argenx, Immunovant, Johnson & Johnson, and UCB. Speaker for Alexion, argenx, Takeda, and UCB. **Kavita Gandhi, Ibrahim Turkoz, Zia Choudhry, Wim Noel, Charlotte Gary,** and **Sindhu Ramchandren:** Employees of Johnson & Johnson, may hold stocks/stock options in Johnson & Johnson. **Maria Ait-Tihyaty:** Employee of Johnson & Johnson at the time of the study and is a current employee of Dianthus Therapeutics. Previously presented at the 11th Congress of the European Academy of Neurology; Helsinki, Finland; June 21–24, 2025